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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/539,497 | 06/17/2005 | Hui Dong | CNIP-C-PCT-US | 2444 |
| 7590 | 10/26/2006 | | EXAMINER | |
| Daniel J. Hudak Hudak Shunk & Farine Co. Suite 307 2020 Front Street, Cuyahoga Falls, OH 44221 | | | MCCORMICK, MELENIE LEE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1655 | |
| DATE MAILED: 10/26/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/539,497 | DONG, HUI |
| | Examiner | Art Unit |
| | Melenie McCormick | 1655 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 October 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
 - 4a) Of the above claim(s) 7-12 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6 and 13-14 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on 10/02/06 has been acknowledged.

Claims 1-6 and 13-14 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-6 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 3 at line 2, addition of the phrase "adding an *Epimedium* herb to an absorption column" is considered new matter. The specification does not support a method of extraction of *Epimedium* wherein the first step is adding the herb to an absorption column. The instant specification teaches that the *Epimedium* herb is first extracted with ethanol and then added to an absorption column (see e.g. page 6-specification), but not that the *Epimedium* herb is added directly to an absorption column as the claims suggest.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Throughout the claims, percentage values are recited. It is not clear, however, if these percentages are referring to a value which is a percentage by weight, by volume, or something else.

In claim 1, lines 5-6, the phrase "the total flavones of the extracts range from 20% to 90%" renders the claim vague and indefinite. It is not clear if the percentage is a value which is measured by weight of the total extract or something else.

In claim 2, lines 4-5, the phrase "the total flavones comprise 10% to 90% of icariin and icariin I" renders the claim vague and indefinite. It is not clear is the 10% to 90% of icariin and icariin I are within the 20% to 90% of total flavones of claim 1 or something else.

Claim 3 is rendered vague by the phrase "recovering the organic solvent from a filtrate" in lines 5-6. It is not clear where the filtrate came from. It is suggested that the phrase " and filtering the extract to obtain a filtrate" be added before the word "recovering" to more clearly define the method. Also in claim 3, lines 9-10, the phrase "wherein the total flavones in the *Epimedium* elute residue are about 20% to 90%" renders the claim vague and indefinite. What are the flavones about 20% to 90% of? In line 13, the phrase "concentration of 70% to

85%" renders the claim vague and indefinite. It is not clear what the concentration of 70% to 85% is of.

Claim 5 appears to be an alternative embodiment of the method of claims 3 and 4, but is in improper form. The claim as a whole is confusing and it is not clear what order the steps recited in the claim are in. To more clearly define this claim, it is suggested that it be rewritten to more clearly define the method being claimed. In claim 5, the claim is also rendered vague and indefinite by the phrase "concentration of 70% to 85%" in line 5. It is not clear what the concentration of 70% to 85% is of.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chen et al. (US 6,123,944) for the reasons set forth in the previous office action and restated below.

The claims are drawn to a composition of *Epimedium* extracts comprising flavones and polysaccharides in ratios varied from 2:8 to 8:2 by weight which are used in treatment of prostatic hyperplasia and wherein the total flavones of the extracts are in the range of 20-90%, and the molecular weights of the polysaccharides vary from 1,000 to 700,000 Daltons.

Chen et al. (US 6,123,944) disclose an icariin-containing preparation obtained from the aerial parts of plants of the *Epimedium* genus (see e.g. col 1, lines 30-32). Chen et al. further disclose that the preparation contains about 15% to about 95% icariin by weight and about 5% to about 80% of non-icariin flavones by weight (see e.g. col 1, lines 32-36). These values overlap with the range of icariin and total flavones of the extracts instantly claimed. The extract taught by Chen et al. would inherently contain polysaccharides of the molecular weights instantly claimed, as it is not indicated by Chen et al. that the polysaccharides have been removed. Consequently, the claimed composition of *Epimedium* extract appears to be anticipated by the reference.

In the alternative, even if the claimed extract composition is not identical to the referenced extract composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is

claimed are considered to be so slight that the referenced extract composition is likely to inherently possess the same characteristics of the claimed extract composition particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed extract composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

With respect to the art rejection above, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' composition differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Applicants argue that the claims are drawn to a composition comprising Epimedium extracts for use in the treatment of prostatic hyperplasia, while the reference does not disclose such use. With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Please note that when applicant claims a composition in terms of function and the composition of the

prior art appears to be the same, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection (MPEP 2112).

Applicants further argue that the instantly claimed composition is not identical or otherwise obvious over the composition taught by Chen et al. because the instantly claimed composition contains the distinctive, inventive characteristic of polysaccharides with molecular weights from 1,000 to 700,000 Daltons. Because the claims do not specifically recite a limitation which states that polysaccharides below 1,000 Daltons and above 700,000 Daltons have been removed, the instantly claimed composition still reads on that disclosed by Chen et al. While the instantly claimed composition contains polysaccharides from 1,000 Daltons to 700,000 Daltons, as currently drafted, the claims read on compositions which may contain additional polysaccharides. Thus, the rejection is deemed proper and is maintained.

To more clearly distinguish the instantly claimed composition from that of the prior art of reference, it is suggested that the phrase "wherein polysaccharides below 1,000 Daltons and above 700,000 Daltons have been removed" be added to the claim.

Claim Objections

Claims 13-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



CHRISTOPHER R. TATE
PRIMARY EXAMINER